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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,888	08/20/2001	Michael E. Spurlock	PM-8935-A	7993
54704 7590 12/27/2006 LAW OFFICE OF PHILLIP F. FOX 10985 40TH PLACE NORTH PLYMOUTH, MN 55441			EXAMINER SAOUD, CHRISTINE J	
			ART UNIT	PAPER NUMBER
			1647	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/27/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 09/932,888	Applicant(s) SPURLOCK ET AL.	
	Examiner Christine J. Saoud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-122 is/are pending in the application.
- 4a) Of the above claim(s) 122 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 88-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 October 2006 has been entered.

Response to Amendment

Claims 1-87 are cancelled and claims 88-122 have been added. Claims 88-122 are pending in the instant application.

Claim 122 is directed to an isolated protein, which is an invention that has been previously withdrawn from consideration. See Restriction Requirement of 07 March 2003 and election, with traverse, on 07 July 2003. Accordingly, claim 122 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03

Therefore, claims 88-121 are under examination in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 04 October 2006 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

Claims 88-122 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

In the most recent amendment, Applicant has canceled all the previously pending claims and added all new claims. Applicant did not identify in the specification by page and line number the basis for the new claim limitations. After a review of the specification as originally filed, basis for the new claim limitations could not be found. For example, the concept of 2 regions of a nucleic acid of SEQ ID NO:1, "identity with at least sixty percent of corresponding nucleotide bases at positions", "identity with at least eighty percent of corresponding nucleotide bases at positions", "identity with at least ninety percent of corresponding nucleotide bases at positions", "identity with at least ninety five percent of corresponding nucleotide bases at positions", recitations of nucleic acid positions which could be variable, recited hybridization conditions with optional

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combinations or for "low salt concentration of 0.99 M sodium ion", and "an isolated single-stranded DNA molecule, a complimentary RNA strand of the single-stranded DNA molecule". The claims must find basis in the specification as originally filed and Applicant must point out support for the new claim limitations. Therefore, the claims are considered new matter.

Claims 52-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record as applied to previously examined claims 13-30 and 39-51. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims are generically directed to isolated DNA and RNA (single and double-stranded) which encode bovine leptin, wherein the nucleic acid molecule hybridizes to a nucleic acid sequence of SEQ ID NO:3 (or a variant thereof) under stringent hybridization conditions. However, the only such molecule disclosed in the instant specification is the nucleic acid molecule of SEQ ID NO:3 which encodes the protein of SEQ ID NO:4.

Applicant argues at page 14 that they are "in actual possession of a bovine leptin genus" and that the "genus of DNA sequences are unique from murine and human at positions 2, 5, 92, 131, 146, 147, 176, 182, 183, 225, 279, 280, 302, 311, 313, 322, 333, 340, 356, 368, 401, 404, 414, or 444 of SEQ ID NO:3". Applicant's argument has been fully considered, but is not persuasive. The specification teaches a single bovine leptin

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molecule. A single bovine leptin molecule does not constitute a genus. The specification does not provide written support for the claims which recite these positions (see rejection above for new matter), nor does the instant specification teach any additional bovine leptin molecule which differ at these positions. Therefore, Applicant's argument is not persuasive.

As stated in the previous Office action(s), If one of ordinary skill in the art would not know the bovine leptin sequence until they were in possession of the bovine leptin sequence (as stated by Dr. Spurlock in a 1.132 Declaration, filed 01/18/01 in parent application 08/688,908), it is unclear how the instant claims meet the written description requirement when the specification provides one bovine leptin sequence, but is claiming a vast genus of molecules which have not been isolated or described. Even if one of ordinary skill in the art could use the disclosed polynucleotide sequence to hybridize to bovine polynucleotides, the skilled artisan would not know if they were in possession of bovine leptin as stated so clearly by the inventor himself.

Claims 88-121 are rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are not enabled for molecules which hybridize and encode a porcine leptin. There is no requirement that the molecules which hybridize do so to a complete

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coding region for porcine leptin – this encompasses fragments and the specification is not enabled for fragments which encode a porcine leptin. There are no examples of a single variant of porcine leptin in the instant specification, and there is a but a single example of a porcine leptin in the instant specification. While the skill in the art is high, there is no guidance or direction provided in the instant specification for making mutations or variations to the given coding sequence; there is no disclosure of which regions of the molecule should be conserved or which regions could be variable. Based on the teachings of the prior art, one might expect that the nucleic acid encoding porcine leptin could be varied to some degree, but would this molecule still be considered a “porcine” leptin? If the nucleic acid is not present in the pig, can it still be considered porcine leptin. Or if the starting material is from pig, and the molecule is mutated such that it now has the sequence of the human molecule, is it still considered “porcine” leptin? Regardless, the issue is that based on the lack of guidance in the specification and the prior art, the lack of examples, and the degree of unpredictability in the art, the claims are not enabled for the full breadth of the claims, absent evidence to the contrary.

At pages 13-15, Applicant continues to argue which has been rendered moot by cancellation of the claims. Even though the rejection which was based on these claims is no longer at issue, it seems important to clarify the record.

Applicant argues that the Kennes article demonstrates that the scientific literature does indeed recognize nucleic acid molecules having at least about 20 bases of a

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nucleotide sequence derived from a leptin gene that encodes a leptin molecule.

Applicant's argument has been considered, but is not persuasive. The issue the Examiner was raising was not directed to the meaning of the term "encode", but rather with the recitation that the encoded molecule be "leptin". For clarity sake, the molecule of Kennes et al which "encodes leptin" is much longer than 20 bases. If leptin is roughly 145 amino acids long, it would require at least 435 nucleotides to encode for the protein. The molecules of Kennes et al. have many more nucleotides, based on the location of the polymorphisms found (i.e. positions 2845, 3996, 2728, 3469). Therefore, on its face, the specification does not teach a polynucleotide as short as 20 bases in length which also encodes porcine leptin. The claims previously recited "at least about 20", but the claims must be enabled for their full breadth, and the lower limit of 20 was not enabled. This argument is moot in light of cancellation of the claims which included this limitation.

Applicant again argues rejections which have been obviated by the cancellation of the claims (see pages 15-17 with regard to "at least about").

Claim Rejections - 35 USC § 112/2nd

Claims 88-121 are indefinite for the limitation of "stringent hybridization conditions". The limitation "stringent hybridization conditions" is equivalent to reciting a range without indicating the metes and bounds of the conditions since there is no indication of what conditions are to be encompassed by the claims. The specification does not provide a definition of what conditions are considered "stringent" and the art

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recognizes a multitude of conditions which could be used and considered "stringent". Because a multitude of conditions are encompassed by the claims, it is not clear which molecules which may hybridize under varying conditions are encompassed by the claims. Many of the claims recite a variety of conditions and indicate that any of the conditions in any combination or all of the conditions are included. This still does not set forth a "set of conditions" by which the nucleic acid molecules will be isolated, therefore, there are still variables unaccounted for which will greatly affect which molecules will hybridize and which will not. Therefore, the metes and bounds of the claims are unclear and the claims are indefinite.

Applicant continues to argue this rejection at pages 17-22. Applicant states at page 21 of the response that "one of ordinary skill in the art will recognize the objective of the claimed invention and would have the knowledge to choose from a variety of conditions to obtain the stringent conditions required to obtain the ***appropriate final result***" (emphasis added). Herein lies the problem. Without a finite, definite set of conditions, which one of ordinary skill in the art is aware, it is unclear if an "appropriate final result" has been met. The purpose of a definite claim is so that one of ordinary skill in the art knows if they are infringing a patented claim or not. What is considered "appropriate" to Applicant, may be considered new and novel to one of ordinary skill in the art. The metes and bounds of the claims must be clear, and the current claims recite open-ended ranges for obtaining molecules, which makes it impossible to determine if the limitations of the claims are met. Therefore, the claims are indefinite for these reasons and the reasons presented in the previous Office actions.

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Applicant argues at pages 22-23 rejections which has been obviated by cancellation of the claims. Applicant's continued argument is moot, as the issue is no longer applicable to the instant claims.

Claims 102-106 and 112-121 are indefinite for reciting both, an isolated single-stranded DNA molecule and a complimentary RNA strand of the single-stranded DNA molecule. It is not clear if the claims are directed to (1) isolated single-stranded DNA, (2) complimentary RNA, (3) or a complex of the two molecules. Take claim 66 for example, there is no disclosed relationship between the DNA molecule in line 1 and the RNA molecule in line 3.

Based on this ambiguity, no art rejections of these claims can be made at this time. If the claims are amended to clearly indicate that RNA molecules are encompassed, an art rejection may be necessitated by such an amendment.

Claim Rejections - 35 USC § 103

Claims 88-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Pat. No. 6,309,853) for the reasons of record in the previous Office action(s) as applied to the previously filed claims.

Applicant argues at page 26 that the Friedman patent does not teach, suggest, disclose, or make obvious the invention and that the Friedman patent does not disclose any porcine leptin DNA (or mRNA) molecules or polypeptides.

Applicant's argument has been fully considered, but is not persuasive. Friedman et al. teach that the nucleic acid molecules encoding leptin could be used to isolate nucleic acid molecules encoding leptin from other species, specifically pigs (see column 48, lines 41-57), contrary to Applicant's assertion that "the Friedman patent does not teach, suggest or disclose the invention of the above-identified application". The claims are broadly directed to isolated nucleic acids which encode porcine leptin – based on the known high degree of nucleic acid similarity of the leptin molecules across species (taught in Friedman), the known existence of a porcine leptin molecule (taught in Friedman), motivation to isolate nucleic acid molecules encoding porcine leptin (taught in Friedman) and known methods of isolation of nucleic acid molecules encoding leptin using one species as a probe (taught in Friedman), the invention as a whole would have been *prima facie* obvious in view of Friedman. If one of ordinary skill in the art used the polynucleotides of Friedman et al. to hybridize to porcine polynucleotides using the methods taught in Friedman et al., there is more than a reasonable expectation of success in isolating a porcine version of leptin, especially since Friedman already confirmed that there was a polynucleotide encoding leptin present in pigs, absent evidence to the contrary. Applicant has not provided any evidence on the record that one of ordinary skill in the art could not follow the teachings and guidance in Friedman et al. to isolate nucleic acids encoding leptin in pigs. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

Applicant argues at pages 26-27 that the biological activities of porcine leptin and human leptin are different and that the nucleic acids of Friedman do not encode proteins with similar functional properties. Applicant's arguments have been fully considered, but are not persuasive.

Applicant's arguments regarding specific activities of porcine leptin are noted, but do not avoid the rejection of record. The claims do not require these specific activities and the specification does not disclose these activities. The functions contemplated by the specification would include any function, such as binding to a leptin receptor, antigenicity, etc. Therefore, Applicant's arguments are not persuasive.

Applicant argues that "the Examiner switched horses and basically alleged Applicants could only consider functional properties disclosed for porcine leptin in the present application" (see page 27 of the response). Applicant's arguments have been considered, but are not persuasive. The claims do not require the isolated molecule to encode a porcine leptin with any particular biological activity. If one of ordinary skill in the art used the polynucleotides of Friedman et al. to hybridize to porcine polynucleotides using the methods taught in Friedman et al., there is more than a reasonable expectation of success in isolating a porcine version of leptin, especially since Friedman already confirmed that there was a polynucleotide encoding leptin present in pigs, absent evidence to the contrary.

Applicant argues at page 28 that the Examiner merely makes conclusions and does not properly reject the claims under 103. In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning,

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it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the rejection was based on the disclosure of Friedman, the success Friedman had in isolating a different species of leptin while using another species as a probe, the disclosure that leptin existed in pigs, and the specific statement of motivation in Friedman to isolate the molecules from other species, including pigs, and the very methods necessary to achieve this goal. Applicant has not provided any evidence on the record that one of ordinary skill in the art could not follow the teachings and guidance in Friedman et al. to isolate nucleic acids encoding leptin in pigs. The fact that the encoded protein has some very specific biological properties in the pig is interesting, but not persuasive for the reasons given above and does not avoid the rejection of record.

Applicant argues at page 29 that based on "known differences between functional attributes of porcine leptin and murine leptin, one of ordinary skill in the art would not expect the functional characteristics of the murine leptin discussed in the Friedman patent would be helpful for confirming isolation of a nucleic acid molecule encoding for porcine leptin". Applicant's arguments are fully considered, but not persuasive. The rejection is one of obviousness and it is based at the time of the instant invention. The functional attributes that Applicant is relying on were only

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discovered after porcine leptin was isolated and characterized. The fact that the molecule was porcine leptin was not obscured by some very species specific characteristics of the porcine leptin molecule. One of ordinary skill in the art at the time the invention was made could have tested the suspected porcine leptin molecule by seeing if it bound to a leptin receptor and stimulated the receptor. Therefore, Applicant's arguments are not persuasive.

Applicant argues at pages 28-29 that the Examiner merely makes conclusions and does not properly reject the claims under 103. In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill in the art at the time the claimed invention was made, and does not include knowledge gleaned only from applicant's disclosure such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the rejection was based on the disclosure of Friedman, the success Friedman had in isolating a different species of leptin while using another species as a probe, the disclosure that leptin existed in pigs, and the specific statement of motivation in Friedman to isolate the molecules from other species, including pigs. Therefore, all the elements necessary to make the rejection under 103 were found in Friedman et al, including an expectation of success based on Friedman's success in isolating one species of leptin using another species of leptin as a probe and the knowledge that leptin existed in the pig based on the results of the zoo

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blot which are included in Friedman's disclosure. Applicant has not provided any evidence on the record that one of ordinary skill in the art could not follow the teachings and guidance in Friedman et al. to isolate nucleic acids encoding leptin in pigs. The fact that the encoded protein has some very specific biological properties in the pig is interesting, but not persuasive for the reasons given above and does not avoid the rejection of record.

Applicant argues at page 29 of the response that U.S.S.N. 08/692,922 teaches away from the claimed invention because the porcine nucleic acid sequence is different from both the murine and the human sequences. However, the instant claims were not rejected over Friedman et al. based on modification/mutation of the Friedman et al. sequences to arrive at the porcine nucleic acid molecules. The rejection is based on the fact that Friedman et al. teach isolation of nucleic acid molecules encoding leptin protein from other species, using the human and/or murine nucleic acids as probes for said nucleic acid molecules. Applicant is arguing at page 30 of the response that the specifics of the porcine nucleotide sequence of the instant application could not be predicted from the disclosure of Friedman et al. Applicant is correct in this statement, which is why a patent was granted on the isolated nucleic acid molecule encoding porcine leptin which is disclosed in the instant application. However, this is not what Applicant is currently claiming. Applicant is arguing limitations which are not in the claims – the claims are directed to a genus of nucleic acid molecules which hybridize to a given nucleic acid sequence under a recited set of hybridization conditions. The point of the current rejection is that under the conditions of the instant claims, the molecule

which would be isolated are obvious over Friedman et al. because Friedman et al. teach nucleic acid molecules encoding leptin from human and mouse, and Friedman et al. teach isolation of leptin from other species, including pigs, and those molecules which are encompassed by the instant claims would also hybridize and be isolated using the nucleic acid molecules of Friedman et al., absent evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud